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Docket No.: 3749-0111PUS1  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Yasuhiro NISHIDA et al.

Application No.: 10/579,338

Confirmation No.: 1932

Filed: May 15, 2006

Art Unit: N/A

For: NOVEL CAROTENOID HYDROXYLASE  
GENE, METHOD FOR PREPARING  
HYDROXYLATED CAROTENOID, AND  
NOVEL GERANYLGERANYL  
PYROPHOSPHATE SYNTHASE

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Examiner: Not Yet Assigned

**LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Subsequent to the filing of the above-identified application on May 15, 2006, attached hereto is an English translation of the International Preliminary Report on Patentability (Forms PCT/IB/338; PCT/IB/373 and PCT/ISA/237) that should be made of record in the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No. 02-2448 for any


Application No.: 10/579,338

Attorney Docket No.: 3749-0111PUS1

additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: SEP 14 2006

Respectfully submitted,

By   
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Attachments

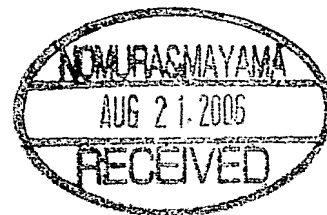
From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

NOMURA, Kenichi  
Nohki-kaikan Fourth Floor  
30-1, Tsuruyacho 3-chome  
Kanagawa-ku, Yokohama-shi  
Kanagawa 221-0835  
JAPON



Date of mailing (day/month/year) 03 August 2006 (03.08.2006)	<b>IMPORTANT NOTIFICATION</b>
Applicant's or agent's file reference FP-042PCT	
International application No. PCT/JP2004/016297	International filing date (day/month/year) 04 November 2004 (04.11.2004)
Applicant MARINE BIOTECHNOLOGY INSTITUTE CO., LTD. et al	

## 1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

## 2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

## 3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

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Authorized officer

Masashi Honda

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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference FP-042PCT	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/JP2004/016297	International filing date ( <i>day/month/year</i> ) 04 November 2004 (04.11.2004)	Priority date ( <i>day/month/year</i> ) 18 November 2003 (18.11.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant MARINE BIOTECHNOLOGY INSTITUTE CO., LTD.		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a).																								
2.	This REPORT consists of a total of 6 sheets, including this cover sheet.																								
In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																									
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention																							
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																							
<input type="checkbox"/>	Box No. VI	Certain documents cited																							
<input type="checkbox"/>	Box No. VII	Certain defects in the international application																							
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																							
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 27 July 2006 (27.07.2006)
Facsimile No. +41 22 338 82 70	Authorized officer <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Masashi Honda</div>
e-mail: pt08@wipo.int	

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

**TRANSLATION**

**PCT**

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing  
(day/month/year)

Applicant's or agent's file reference

**FP-042PCT**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/JP2004/016297**

International filing date (day/month/year)

**04.11.2004**

Priority date (day/month/year)

**18.11.2003**

International Patent Classification (IPC) or both national classification and IPC

Applicant

**MARINE BIOTECHNOLOGY INSTITUTE CO., LTD.**

1. This opinion contains indications relating to the following items:

- |                                     |              |                                                                                                                                                                      |
|-------------------------------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the opinion                                                                                                                                                 |
| <input type="checkbox"/>            | Box No. II   | Priority                                                                                                                                                             |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability                                                                     |
| <input checked="" type="checkbox"/> | Box No. IV   | Lack of unity of invention                                                                                                                                           |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited                                                                                                                                              |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application                                                                                                                     |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application                                                                                                                |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/016297

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☒ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☒ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☒ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 9-17

because:

☐ the said international application, or the said claims Nos. \_\_\_\_\_  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 9-17

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/016297

Box No. IV

Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☐ paid additional fees
- ☐ paid additional fees under protest
- ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with
- ☒ not complied with for the following reasons:

There is no matter common to Claims 1-17.

Consequently, the inventions described in Claims 1-17 can be classified into those of Claims 1-8 having the special technical feature of "a gene coding for a peptide consisting of the amino acid sequence represented by SEQ ID NO:4," those of Claims 9 and 10 having the special technical feature of "the 2,2'-dihydroxy- $\beta$ , $\beta$ -carotene-4,4'-dion(2,2'-dihydroxycanthaxanthin) represented by Chemical Formula (I)," that of Claim 10 having the special technical feature of "an anti-oxidant containing as an active component 2-hydroxy- $\beta$ , $\beta$ -carotene-4,4'-dion(2-dihydroxycanthaxanthin)," those of Claims 11-16 having the special technical feature of "a gene coding for a peptide consisting of the amino acid sequence represented by SEQ ID NO:30," and that of Claim 17 having the special technical feature of "a gene coding for a peptide consisting of the amino acid sequence represented by SEQ ID NO:32".

Thus, Claims 1-17 describe 5 general inventive concepts, and since these respective general inventive concepts do not share any novel special technical feature, this application does not appear to fulfil the requirement of unity of invention (Enforcement Rule 13 (PCT Rules 13.1, 13.2 and 13.3)).

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☐ all parts
- ☒ the parts relating to claims Nos. 1-8



**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2004/016297

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-8	YES
	Claims		NO
Inventive step (IS)	Claims	1-8	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2. Citations and explanations:

Document 1: Biosci. Biotech. Biochem., 1996, Vol. 60, No. 2, pp. 200-203  
 Document 2: PNAS, 2001, Vol. 98, pp. 4136-4141  
 Document 3: J. Biol. Chem., 1997, Vol. 272, pp. 6128-6135  
 Document 4: WO 2002/79395 A2 (Cargill, Incorporated, USA), 10 October 2002, examples

The inventions described in Claims 1-8 appear to be novel and to involve an inventive step over documents 1-4.

Document 1 describes that a dye having a hydroxyl group introduced into the 2-position carbon of the  $\beta$ -ionone ring was extracted from cultured cells of the marine bacterial strain SD-212 (Abstract, Fig. 1).

Document 2 describes the total genome sequence of *Calobacter crescentus* (GenBank: Accession No. AE005673), and the amino acid sequence shown by gene #CC1671, which is accessed by the accession number for this sequence, has homology with the amino acid sequences represented by the sequence ID numbers in the claims.

Document 4 describes the cloning of a  $\beta$ -carotene C4 oxygenase gene derived from *brevundimonas aurantiaca*, the nucleotide sequence of the gene (crtW gene) coding for this enzyme, and the amino acid sequence of the protein coded for by this gene (SEQ ID NOS:38,39).

The peptide consisting of the amino acid sequence represented by SEQ ID NO:4 and the peptide coded for by DNA consisting of the nucleotide sequence represented by SEQ ID NO:3 which are described in the claims have  $\beta$ -ionone ring-2-hydroxylase activity, and this matter is neither described or suggested in any of documents 1-4, nor would it be obvious to a person skilled in the art.